REMARKS

This Amendment is filed in response to the Official Action mailed June 30, 2006. In this Amendment, claims 36, 37, 39, and 42 are amended and claims 38, 40-41, and 43-44 are unchanged. Following entry of this amendment, claims 36-44 shall be pending.

In the Office Action, claim 36 is objected to because of an informality, and claims 36-44 have been rejected based on prior art grounds. For the reasons set forth below, these rejections are hereby traversed.

I. Objection Under § 132(a)

The Examiner continues to object to the Amendment filed on September 2, 2005 under 35 U.S.C. § 132(a) and asserts that claim 36 as introduced by that Amendment adds new matter into the disclosure. Specifically, the Examiner asserts that "the added material which is not supported by the original disclosure is as follows: 'supportively engaging the medicament delivery catheter with the atrial septum at the openings....'"

In this regard (and without conceding the objection), claim 36 has been amended to recite "supportively engaging the atrial septum at the opening with the medicament delivery catheter and sealing the opening". With respect to this language, support can be found, for example, in paragraph [0151] in the Application as originally filed which states:

> Thereafter, the first balloon 316a and the second balloon 316b are inflated, thereby supportively engaging the tissue 308a disposed therebetween.

Thus, the Applicant asserts that the specification as filed supports the language of claim 36 and that the objection under 35 U.S.C. Section 132(a) should be withdrawn.

II. Rejections Under 35 U.S.C. Section 112

Claims 36-38 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that these claims contain subject matter that is not described in the specification, specifically the language "supportively

engaging the medicament delivery catheter with the atrial septum at the opening and sealing the opening."

With respect to claims 36-38, independent claim 36 has been amended as previously discussed with regard to the objection under 35 U.S.C. Section 132(a). The Applicant traverses the rejection and reiterates the citation to paragraph [0151] of the specification as filed. The originally filed disclosure is not silent as to the currently recited claim language, thus the specification reasonably conveys to one skilled in the art that the Applicant had possession of the claimed invention at the time the Application was filed.

Claims 36-38 stand rejected under 35 U.S.C. § 112, second paragraph, as failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner asserted that various recited words had improper antecedent basis. Claim 36 has been amended and is now believed to avoid any questions concerning antecedent basis for the elements of this claim. The Examiner also asserts that words of claim 45 also include improper antecedent basis. However, claim 45 was canceled in a previous amendment.

III. Rejections Under 35 U.S.C. Section 102

Claims 42-44 have been rejected under 35 U.S.C. Section 102(e) as being anticipated by U.S. Patent No. 6,283,951 to Flaherty et al. For at least the reasons set forth below, it is submitted that these prior art rejections should be withdrawn and the pending claims allowed.

Claim 42 is directed to a method of delivering medicament to tissue while preventing medicament washout, comprising: providing a medicament delivery catheter having a tissue engaging surface with a sealing balloon; providing access to a tissue surface; advancing the catheter to the tissue surface; positioning the tissue engaging surface proximate the tissue surface; sealably engaging the tissue engaging surface to the tissue surface by inflating the sealing balloon; forming a sealed opening in the tissue surface; delivering medicament through the sealed opening in the tissue surface; and preventing the medicament from passing between the tissue engaging surface and the tissue surface to a location outside of the sealed opening [emphasis added].

In response to the Applicants arguments in the Amendment dated March 27, 2006, the Examiner asserts that:

> The balloon of Flaherty et al. clearly performs a sealing function, as it pushes against the tissue to distend it. Thus it is unclear how applicant can assert that the balloon does not seal the tissue when pressure is applied thereto by the balloon from maintaining pressure. The mere fact that medicament can leak out slowly does not prevent the balloon from maintaining pressure. (Office Action dated June 30, 2006, p. 2)

In this regard, the Examiner acknowledges that medicament can, at the very least, "leak out" by way of the porous balloon, but incongruously argues that the porous balloon can somehow seal an opening despite these holes. This assertion ignores the meaning of the word "sealably" as used in claim 42. For example, a common definition of "seal" according to the 2006 Encarta World English Dictionary is, "a tight closure that prevents the entrance or escape of, e.g. air or water, or a substance or device that forms such a closure." While this exemplary definition is not meant to be limiting, it does emphasize the importance of preventing (as opposed to facilitating or encouraging) entrance or escape of a substance.

The porous balloon of Flaherty et al. is specifically intended to encourage (rather than prevent) the escape or passage of medicament therethrough, as depicted in FIG. 6 and described in relation thereto:

> "The drug delivery catheter 214 may include a porous balloon 218 for infusing the drug in a predetermined pattern within the tissue region 220 . . . . The porous balloon 218 includes a porous region, such as a plurality of holes 226, a permeable region and the like, preferably arranged to provide a predetermined flow pattern through the balloon 218 and into the tissue region 220." (Flaherty et al., col. 13, lines 39-41, 48-52.)

Thus, the porous balloon of Flaherty et al. does not merely "leak" – it is specifically configured to facilitate (rather than prevent) the passage of medicament therethrough. Accordingly, it cannot be seen as a seal.

Flaherty et al. makes provides absolutely no teaching, or even a remote suggestion, that its porous balloon acts as any type of seal. Instead, the porous balloon of Flaherty et al. is specifically described as providing "a predetermined flow pattern" of medication to the

surrounding tissue. Accordingly, the porous balloon of Flaherty et al. is inherently incapable of "sealably engaging a tissue engaging surface to the tissue surface. Thus, Flaherty et al. does not disclose sealably engaging the tissue as recited in claim 42.

Further, even if the porous balloon of the Flaherty et al. device could somehow be considered to seal, it does not prevent the medicament from passing between the tissue engaging surface and the tissue surface to a location outside of the sealed opening as now recited in claim 42. As previously discussed, the porous balloon of Flaherty et al. encourages the escape or passage of medicament through the holes or pores in the balloon's surface.

Thus, for at least these reasons, the Flaherty et al. reference does not anticipate claim 42. It is also submitted that Flaherty et al. does not render the invention obvious.

Turning to claims 43 and 44, these claims depend from claim 42 and thus for at least the above reasons are also novel and unobvious over the cited prior art. However, these claims further limit the claimed invention and thus are separately patentable over the cited prior art.

IV. Rejections Under 35 U.S.C. Section 103

A. Claims 36-38

Claims 36-38 are rejected under 35 U.S.C. Section 103(a) as being anticipated by U.S. Patent No. 6,283,951 to Flaherty et al. in combination with U.S. Patent No. 6,645,199 to Jenkins et al., U.S. Patent No. 6,161,543 to Cox et al., and U.S. Patent Application No. 2001/0049497 to Kalloo et al. For at least the reasons set forth below, it is submitted that these prior art rejections should be withdrawn and the pending claims allowed.

With regard to claims 36-38 rejected under section 103(a), there is not a *prima facie* case of obviousness since no specific motivation to combine the references has been shown. In other words, improper hindsight appears to have been used in combining these references. As stated in 2143.01 of the MPEP:

> The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990) (Claims were directed to an apparatus for producing an aerated cementitious

> composition by drawing air into the cementitious composition by driving the output pump at a capacity greater than the feed rate. The prior art reference taught that the feed means can be run at a variable speed, however the court found that this does not require that the output pump be run at the claimed speed so that air is drawn into the mixing chamber and is entrained in the ingredients during operation. Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." 916 F.2d at 682, 16 USPQ2d at 1432.). See also *In re Fritch*, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992) (flexible landscape edging device which is conformable to a ground surface of varying slope not suggested by combination of prior art references)...
>
> A statement that modifications of the prior art to meet the claimed invention would have been "'well within the ordinary skill of the art at the time the claimed invention was made'" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). See also *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000) (Court reversed obviousness rejection involving technologically simple concept because there was no finding as to the principle or specific understanding within the knowledge of a skilled artisan that would have motivated the skilled artisan to make the claimed invention); *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999) (The level of skill in the art cannot be relied upon to provide the suggestion to combine references.). [Emphasis added]

Even if it were somehow possible to physically combine the elements of the four references, the Examiner has not identified any specific evidence in the prior art of motivation to combine them. As discussed above, simply providing elements of a claim from different prior art references and suggesting it is desirable to combine their elements is NOT sufficient to establish a *prima facie* case of obviousness. The Examiner must point to specific instances within the prior art that suggest such a desirability. Since specific suggestions of desirability have not been provided, the Examiner has not established a *prima facie* case of obviousness.

Even if such a combination could be asserted, however, the combined references still do not show or render obvious the present invention as recited in claim 36. For example, Flaherty et al. does not teach supportively engaging the atrial septum at an opening with the medicament delivery catheter and sealing the opening with the medicament delivery catheter. To remedy this deficiency, the Examiner asserts that "Cox et al. teach the use of means to seal the tissue around an internal chamber ablation device to prevent bleeding when working on a bleeding

heart." However, as seen in column 27, lines 9-21 of Cox et al., the "means to seal" is performed with sutures, staples or a clamp (i.e., devices distinct from the catheter and which are not delivered by the catheter). In other words, the sealing taught in Cox et al. requires additional tools and distinct devices which are not integrated into a single method as in the presently claimed invention. Thus, contrary to the Examiner's assertion, Cox et al. does not show supportively engaging the atrial septum at an opening with the medicament delivery catheter and sealing the opening with the medicament delivery catheter as claimed.

Neither does Kalloo et al. show supportively engaging the atrial septum at an opening with the medicament delivery catheter and sealing the opening with the medicament delivery catheter as claimed. The Examiner asserts that "Kalloo et al teach the use of a dual balloon stabilizing means to aid in the placement of a surgical device." However, simply combining the balloons of Kalloo et al. will not achieve the invention as recited in claim 36. The device of Kalloo et al. is directed to performing a procedure within a stomach with an endoscope (transgastric peritoneoscopy). While the device of Kalloo et al. may include balloons, these balloons are sized and configured for use with the stomach and therefore include a relatively large diameter, large thickness, and greater distance between both balloons. Therefore, these balloons cannot simply be placed on a device appropriately sized for a cardiac procedure as the Examiner suggests without some additional teaching as to how such an adaptation may be performed.

Jenkins et al. does not make up for this deficiency. Jenkins et al. is directed to a method of pushing an electrode loop with an expandable structure to create a circumferential lesion to treat atrial fibrillation. While Jenkins et al. may suggest a maize technique for ablating a portion of the heart, it does not make up for the lack of sealing of Flaherty et al. because the Jenkins et al. reference does not teach supportively engaging the atrial septum at an opening with the medicament delivery catheter and sealing the opening with the medicament delivery catheter. In this respect, Jenkins et al. fails to teach any type of sealing device and therefore does not make up for the deficiency of Flaherty et al. and Mueller.

Hence it is clear that Jenkins et al., Cox et al., Kalloo et al., and Flaherty et al. do not render claim 36 or its dependent claims 37-38 obvious. Accordingly it is submitted that the rejection of claims 36-38 should be withdrawn.

B. Claims 39-40

Claims 39 and 40 are rejected under 35 U.S.C. Section 103(a) as being obvious in view of U.S. Patent No. 6,283,951 to Flaherty et al. in combination with U.S. Patent No. 6,645,199 to Jenkins et al. and U.S. Patent No. 5,725,523 to Mueller. The rejection is respectfully traversed, as discussed below.

No specific motivation or suggestion to combine the three references has been shown. In other words, improper hindsight appears to have been used in arriving at the proposed combination. As quoted above in 2143.01 of the MPEP, simply providing elements of a claim from different prior art references and suggesting it is desirable to combine their elements is not sufficient to establish a *prima facie* case of obviousness. The Examiner must point to specific instances within the prior art that suggest such a desirability. Since specific suggestions of desirability in the prior art have not been provided, the Examiner has not established a *prima facie* case of obviousness. The cited references in fact teach away from the proposed combination, in that combining the vacuum of Mueller with the porous medicament-dispensing balloon of Flaherty et al. would inherently defeat the medicament-dispersing purpose of the Flaherty et al. balloon. Applying a vacuum to the porous balloon of Flaherty et al. would prevent the desired disbursement of medication through the porous balloon. Such a proposed combination that destroys the purpose of a primary reference is inherently non-obvious.

Even if there were some motivation to combine the cited references, the proposed combination of Flaherty et al. with Jenkins et al. and Mueller cannot be properly relied upon to reject claim 39. For example, as discussed previously, the Flaherty et al. reference with its porous balloon fails to teach or even remotely suggest preventing the medicament from passing between the tissue engaging surface and the tissue surface to a location outside the sealed opening. The Jenkins et al. Patent and Mueller references do not make up for this deficiency. For example, Mueller is directed to a device which creates a seal against an area of tissue by providing suction or a vacuum. This suction, when combined with Flaherty et al., would likely cause the medicament within the porous balloon to be drawn out, reducing the pressure in the porous balloon and further preventing the creation of any sort of seal. Jenkins et al. is directed to a method of pushing an electrode loop with an expandable structure to create a circumferential lesion to treat atrial fibrillation, and clearly lacks teaching or suggestion of any

type of sealing device. Hence, the obviousness rejection based on the combination of Flaherty et al. with Jenkins et al. and Mueller must fail.

Claim 40 depends from claim 39 and thus, for at least the above reasons, is also novel and unobvious over the cited prior art. Moreover, claim 40 further limits the claimed invention and thus is separately patentable over the cited prior art.

C. Claim 41

Claim 41 is rejected under 35 U.S.C. Section 103(a) as being obvious in view of U.S. Patent No. 6,283,951 to Flaherty et al. in combination with U.S. Patent No. 6,645,199 to Jenkins et al., U.S. Patent No. 5,725,523 to Mueller, and further in view of U.S. Patent No. 5,807,388 to Jeevanandam et al. The rejection is respectfully traversed, as discussed below.

As a first matter, no specific motivation or suggestion to combine the four references has been shown. The proposed combination actually destroys the purpose of a primary reference (namely the medicament-dispensing purpose of Flaherty et al.), as discussed above with respect to claim 39. In other words, improper hindsight appears to have been used in arriving at the proposed combination.

Moreover, even if motivation for the proposed combination existed, Claim 41 has limitations which are not met by the proposed combination. For example, claim 41 depends from claim 39 as amended (discussed previously), which recites (among other limitations) preventing the medicament from passing between the tissue engaging surface and the tissue surface to a location outside the sealed opening. As discussed previously, Flaherty et al., Jenkins et al., and Mueller fail to teach or suggest such a feature. Moreover, adding Jeevanandam to the proposed combination does not cure the deficiency. Accordingly, claim 41 is novel and unobvious over the cited prior art.

Petition for Extension of Time to Respond

Pursuant to 37 C.F.R. 1.136(a), Applicant hereby requests an extension of time for **Two Months** to respond to the above-referenced Office Action. The Commissioner is hereby authorized to charge the required fee of $450.00, as well as any additional amounts and/or fees which may be required in connection with this Amendment, to Deposit Account No. 50-1225 (Docket No. CVG-5637).

Conclusion

In view of the foregoing, it is submitted that pending claims 36-44 are now in condition for allowance. Hence an indication of allowability is hereby requested.

If for any reason direct communication with Applicants' attorney would serve to advance prosecution of this case to finality, the Examiner is cordially urged to call the undersigned attorney at the below listed telephone number.

Respectfully submitted,

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